

## **REMARKS**

Claims 1-73 are pending. Claims 1-21, 34, 35 and 66-73 were withdrawn as being directed to a nonelected invention. Claims 4, 7, 11-20, 27 and 51 have been canceled without prejudice or disclaimer to the subject matter claimed therein. Claims 22, 28, 31, 39 and 42 have been amended. New claims 74-87 have been added. Applicants respectfully submit that the new claims are properly categorized in elected Invention Group II.

### **Election/Restriction**

The Examiner acknowledged Applicants' election without traverse of the invention of Group II. The examiner noted that Applicants did not elect a species for generic claims 55-59; therefore the examiner elected a fibrous matrix shaped in a sheet.

### **Claim Rejections – 35 USC §112**

Claims 28 and 29 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite. More specifically, the examiner was unclear about Applicants' definition or usage of the terms "isotropic" and "anisotropic". To expedite prosecution, the examiner defined "anisotropic structure" to mean a structure in which properties differ according to the direction of measurement, while "isotropic" was defined by the examiner as having identical properties in all directions.

Applicants can agree with these definitions. More specifically, Applicants believe that these are the commonly understood definitions of the terms. Thus, this rejection should be moot.

Before addressing the prior art rejections, Applicants believe that a brief review of the invention would be helpful to its understanding.

Applicants have discovered that one way to make a unique fibrous structure suitable for implantation in a body of a living being is to take a slurry containing at least a plurality of biodegradable polymer fibers in a fluid, optionally also containing a lubricant, and to compress the slurry to expel at least some of the fluid. Something remarkable then occurs: the fibers migrate through the remaining fluid and begin to organize themselves into a plurality of layers or plates. The fibers tend to align within a given layer or plate, but the layers or plates themselves are not necessarily aligned with respect to one another. The layers or plates define fluid planes. The fluid planes may not extend across the entire structure, but instead may exist as multiple fissures located randomly throughout the structure. Additional compression brings the layers or plates of fibers into closer contact, allowing them to become locked into a compact anisotropic structure, although the material may be isotropic in two dimensions.

**Claim Rejections – 35 USC §102**

Claims 22-33, 38-45, 47-49, 51-53 and 61-65 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,158,574 to Stone (hereinafter referred to as “Stone”).

Applicants respectfully traverse this rejection.

Applicants respectfully submit that Stone neither discloses nor suggests the claimed invention. Specifically, Stone neither discloses nor suggests the invention of independent claim 22 featuring aligned fibers in the form of layers and/or plates, with fissures or fluid planes between the layers or plates of aligned fibers, and with this architecture occurring substantially throughout the structure. Similarly, Stone neither discloses nor suggests the invention of independent claim 31 directed to an implantable device featuring aligned polymer fibers, and where the polymer fibers on the periphery of the device are cross-linked, but those located away from the periphery are not cross-linked. Likewise, Stone neither discloses nor suggests the invention of independent claim 39 directed to an implantable device featuring fibrous plates in a layered structure, with the layering occurring on both the microscopic as well as the macroscopic level, the fibrous plates being formed by the application of compression to a mixture of fibers and fluid, which causes the alignment of fibers into the plate formation. Moreover, Stone neither discloses nor suggests the invention of independent claim 42 directed to a compressed fibrous matrix featuring multiple plates of oriented fibers, the plates being present throughout the device and being locked in a compact anisotropic structure.

Claims 22-33, 37-48 and 51-65 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent Application Publication No. US2002/0127270 to Li (hereinafter referred to as “Li”). Applicants respectfully traverse this rejection.

Applicants respectfully submit that Li neither discloses nor suggests the claimed invention. Specifically, Li neither discloses nor suggests the invention of independent claim 22 featuring aligned fibers in the form of layers and/or plates, with fissures or fluid planes between the layers or plates of aligned fibers, and with this architecture occurring substantially throughout the structure. Similarly, Li neither discloses nor suggests the invention of independent claim 31 directed to an implantable device featuring aligned polymer fibers, and where the polymer fibers on the periphery of the device are cross-linked, but those located away from the periphery are not cross-linked. Likewise, Li neither discloses nor suggests the invention of independent claim 39 directed to an implantable device featuring fibrous plates in a layered structure, with the layering occurring on both the microscopic as well as the macroscopic level, the fibrous plates being formed by the application of compression to a mixture of fibers and fluid, which causes the alignment of fibers into the plate formation. Moreover, Li neither discloses nor suggests the invention of independent claim 42 directed to a compressed fibrous matrix featuring multiple plates of oriented fibers, the plates being present throughout the device and being locked in a compact anisotropic structure.

**Claim Rejections – 35 USC §103**

Claims 22-33, 36-48 and 51-65 were rejected under 35 U.S.C. §103(a) as being unpatentable over Li. Applicants respectfully traverse this rejection.

The Action states that Li is silent on the use of the membrane as a swellable hemostatic plug but it would be obvious to one skilled in the art at the time of the invention to shape the membrane to the desired dimensions of a plug and since collagen is well known to swell when exposed to water (forming gelatin), it is clearly obvious that such a device could be used as a swellable hemostatic plug.

Applicants respectfully submit that Li neither discloses nor suggests the claimed invention. Specifically, Li neither discloses nor suggests the invention of independent claim 22 featuring aligned fibers in the form of layers and/or plates, with fissures or fluid planes between the layers or plates of aligned fibers, and with this architecture occurring substantially throughout the structure. Similarly, Li neither discloses nor suggests the invention of independent claim 31 directed to an implantable device featuring aligned polymer fibers, and where the polymer fibers on the periphery of the device are cross-linked, but those located away from the periphery are not cross-linked. Likewise, Li neither discloses nor suggests the invention of independent claim 39 directed to an implantable device featuring fibrous plates in a layered structure, with the layering occurring on both the microscopic as well as the macroscopic level, the fibrous plates being formed by the application of compression to a mixture of fibers and fluid, which causes the alignment of fibers into the plate formation. Moreover, Li neither discloses nor suggests the invention of independent claim 42 directed to a compressed fibrous matrix featuring multiple plates of oriented fibers, the plates being present throughout the device and being locked in a compact anisotropic structure.

Applicants respectfully traverse the statement that collagen swells in water to form gelatin. Specifically, this statement is incorrect, as the first degradation product of collagen is gelatin, and is recognized in the art to be distinct from collagen, whether in solution or otherwise. If the examiner merely intended to state that it is known to swell collagen upon exposure to water, Applicants respectfully submit that it is not known to swell collagen having fissures and fluid planes which are rehydrated to cause swelling of the device.

Claims 22-33 and 36-65 were rejected under 35 U.S.C. §103(a) as being unpatentable over Stone in view of Li and further in view of U.S. Patent No. 6,428,576 B1 to Haldimann. Applicants respectfully traverse this rejection.

The Action applied Haldimann primarily to show that the use of plasticizers and particulates in implantable bio-polymers was well known to the skilled artisan at the time of the invention. Applicants respectfully submit, however, that Haldimann fails to remedy the deficiencies in Stone and in Li. Specifically, Haldimann fails to disclose or suggest the invention of independent claim 22 featuring aligned fibers in the form of layers and/or plates, with fissures or fluid planes between the layers or plates of aligned fibers, and with this architecture occurring substantially throughout the structure, and which features are not disclosed or

suggested by Stone or by Li. Similarly, Haldimann fails to disclose or suggest the invention of independent claim 31 directed to an implantable device featuring aligned polymer fibers, and where the polymer fibers on the periphery of the device are cross-linked, but those located away from the periphery are not cross-linked, and which features are not disclosed or suggested by either Stone or by Li. Likewise, Haldimann fails to disclose or suggest the invention of independent claim 39 directed to an implantable device featuring fibrous plates in a layered structure, with the layering occurring on both the microscopic as well as the macroscopic level, the fibrous plates being formed by the application of compression to a mixture of fibers and fluid, which causes the alignment of fibers into the plate formation, and which features are neither disclosed or suggested by either Stone or by Li. Moreover, Haldimann fails to disclose or suggest the invention of independent claim 42 directed to a compressed fibrous matrix featuring multiple plates of oriented fibers, the plates being present throughout the device and being locked in a compact anisotropic structure, and which features are neither disclosed or suggested by either Stone or by Li.

Accordingly, this rejection should be withdrawn

#### **Double Patenting**

Claims 22-26, 29-30, and 36-38 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-11, 15-19 and 21-25 of copending Application No. 10/010,304.

Applicants respectfully traverse this rejection. Applicants respectfully submit that the claimed invention is patentably distinct from the claims of copending Application No. 10/010,304. Specifically, the claims of USSN 10/010,304 are directed to a method of making a porous polymer, but do not expressly recite fibers that are at least partially aligned in the form of layers or plates. Furthermore, the copending Application discloses forming a gel upon the addition of a swelling agent, and is not related to the present application.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

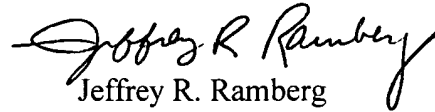
Applicants appreciate the Examiner's having considered the references cited to the Office by Applicants' IDS of August 22, 2005.

Appl. No. 10/729,146  
Amdt. Dated November 23, 2006  
Reply to Office Action of June 23, 2006

In view of the sharply amended claims and the above remarks, Applicants respectfully submit that the instant application is in condition for allowance. Accordingly, Applicants respectfully request issuance of a Notice of Allowance directed to claims 22-26, 28-33, 36-50, 52-65 and 74-87.

Should the Examiner deem that any further action on the part of Applicants would be desirable, the Examiner is invited to telephone Applicants' undersigned representative.

Respectfully submitted,

  
Jeffrey R. Ramberg  
Reg. No. 34,700

November 23, 2006

c/o Kensey Nash Corporation  
735 Pennsylvania Drive  
Exton, PA 19341  
Tel: (484) 713-2140  
Fax: (484) 713-2909